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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,665	02/15/2001	Yiqun Wang	1001.1412101	2225
11050 7590 10/18/2011 SEAGER, TUFTE & WICKHEM, LLC 1221 Nicollet Avenue Suite 800 Minneapolis, MN 55403				
EXAMINER				
DOWE, KATHERINE MARIE				
ART UNIT		PAPER NUMBER		
3734				
MAIL DATE		DELIVERY MODE		
10/18/2011		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

09/784,665

Applicant(s)

WANG ET AL.

Examiner

KATHERINE DOWE

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 22, 24-26, 28 and 30-37 is/are pending in the application.
- 5a) Of the above claim(s) 31-34 and 36 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 22, 24-26, 28, 30, 35 and 37 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____
- Paper No(s)/Mail Date ____

DETAILED ACTION

1. The following is in response to the amendment filed June 29, 2011.
2. Claims 22, 24-26, 28, 30, 35, and 37 are currently pending. Claims 31-34 and 36 have been withdrawn from consideration.

Claim Rejections - 35 USC § 112

3. The amendment to claim 22 is acknowledged. Accordingly, the rejection of the claim under 35 USC 112, first paragraph, as failing to comply with the written description requirement, has been withdrawn.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. Claims 22, 24-26, 28, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsumoto et al. (US 4,610,665, hereinafter "Matsumoto") in view of Picha et al. (US 5,080,654, hereinafter "Picha") and Kranys (US 5,207,656).

Matsumoto discloses the invention substantially as claimed including a catheter (70), comprising: an elongate catheter shaft (71) having a proximal end, a distal end, a guidewire lumen (72) defined therethrough, and an inflation lumen (75) defined therethrough; a balloon (74) disposed adjacent the distal end of the catheter shaft, the balloon being in fluid communication with the inflation lumen; a port (76) disposed at the proximal end of the catheter shaft, the port having an opening defined therein that is in fluid communication with the inflation lumen, and a self-sealing seal member (16) attached to the end of the port and covering the opening (Fig. 16 and 17). The seal (16) is pierceable, is generally planar, and may extend laterally beyond the flanged end of the

port (Fig 11). A cap (78) is coupled to the port and disposed over the seal (Fig 17). Since the seal is self-sealing, upon withdrawal of a piercing member inserted therethrough, the seal member is capable of maintaining a vacuum with the inflation lumen.

However, Matsumoto fails to disclose the seal member is releasably attached to the flanged end. Picha discloses a self-sealing seal member (20) that is releasably attached the flanged end of a port, and the flange helps to secure the elastomeric seal in place (col. 3, ln. 6-42). The seal is pierceable (col. 3, ln. 12 and 56-58), is generally planar at the proximal end (Fig 4), and may extend laterally beyond the flanged end (15) of the port (Fig 4). A cap (30) is coupled to the port and disposed over the seal (Fig. 5). It would have been obvious to one of ordinary skill in the art to modify the seal assembly of Matsumoto such that the seal member was releasably attached to the flanged end, since it is a well known feature as taught by Picha and it would provide the same function of maintaining a fluid-tight seal during insertion of and after removal of an injection member. Substitution of one known element for another element providing the same function to yield predictable results would have been obvious to one of ordinary skill in the art at the time of the invention.

Furthermore, Matsumoto discloses the self-sealing seal member comprises slits (17/18) that form a fluid tight seal about the piercing member (77), wherein the slits have a minimal width and the seal (16) is formed of an elastomeric material such that upon removal of the piercing member (77) the slits form a perfect seal to prevent inflation fluid from flowing out of the balloon. However, Matsumoto teaches the slits (17/18) are pre-formed and thus fails to disclose the seal member has a solid cross-section. Kranys discloses a similar seal (24) disposed in a port of a catheter, wherein the seal comprises multiple pre-formed slits (40) to allow passage of a piercing member (Fig 2). However,

Kranys additionally discloses the seal may alternatively comprise a solid cross section initially with no pre-formed opening (Fig 3). In this second embodiment, a piercing member passes through the seal (24a) to form a slit that exactly fits the transverse dimensions of the piercing member inserted therethrough (col 4, ll 1-7). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the invention of Matsumoto such that the pre-formed slits (17/18) were replaced with a seal member having a self-sealing solid cross-section. Such a modification would further ensure fluid cannot pass through the seal unintentionally. Furthermore, it has been shown a seal with pre-formed slits and a seal with an initial solid cross section without a pre-formed opening are functional equivalents.

6. Claims 35 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsumoto (US 4,610,665), Picha (US 5,080,654) and Kranys (US 5,207,656), as applied to claim 22 above, further in view of McClure (US 5,507,732) and Andrews et al. ("The Comparison of Certain Commercial Getters", 1931). Matsumoto, Picha, and Kranys disclose the invention substantially as claimed, as shown above. However, they do not disclose an inner surface of the lumen includes a chemical coating capable of binding air. McClure discloses a seal arrangement (Fig 1) for use with a typical balloon catheter (col 1, ll 11-23). McClure teaches the purpose of the seal arrangement is to hold pressure under balloon inflation as well as vacuum under balloon deflation (col 4, ll 14-17). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Matsumoto, Picha, and Kranys such that the self-sealing function of the seal member prevented the passage of fluid such that it was capable of both holding pressure under balloon inflation and holding vacuum under balloon deflation. Thus, the balloon will not unintentionally slightly

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deflate after time when it is intended to be inflated or slightly expand over time when it is intended to be completely deflated. Additionally, when referring to the chemical coating capable of binding air, Applicant states, "A person of ordinary skill in the art would be familiar with a getter and the use thereof according to multiple embodiments of the invention." (see specification as originally filed, page 11, lines 8-9). As evidenced by the article, "The Comparison of Certain Commercial Getters" (1931), it is old and well known in the art to apply a chemical coating capable of binding air to a valve/sealing system to improve the vacuum capability of the device. Therefore, it would have been prima facie obvious to try modifying the combination of Matsumoto, Kranys, Picha, and McClure such that the an inner surface of the lumen includes a chemical coating capable of binding air in an attempt to provide an improved vacuum as a person with ordinary skill has good reason to pursue the known options within his or her technical grasp and since it is obvious to choose from a finite number of identified, predictable solutions with a reasonable expectation of success.

Response to Arguments

7. Applicant's arguments, see amendment, filed June 29, 2011, with respect to the rejection(s) of claim(s) 22, 24-26, 28, 30, 35, and 37 under Rauker (US 6,475,185) have been fully considered and are persuasive. Applicant states Rauker and the current application were commonly owned or subject to an obligation of assignment to the same person at the time the claimed invention was made. Thus, Rauker is not available as prior art under 35 USC 103(c). Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Kranys (US 5,207,656).

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine Dowe whose telephone number is (571) 272-3201. The examiner can normally be reached Monday through Friday, 8:30am – 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, Gary Jackson, at (571) 272-4697.*** The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to

TC3700_Workgroup_D_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Katherine M Dowe/
Examiner, Art Unit 3734

October 11, 2011